July 12, 2001

Ivan Linscott, Chairman
Shoshone Natural Resources Coalition, Science Committee
P.O. Box 1027
Wallace, Idaho 83873

Dear Dr. Linscott:

Thank you for expressing concerns about the *Human Health Risk Assessment for the Coeur d'Alene Basin extending from Mullan to Harrison* (HHRA). The issues presented at the Science Summit and subsequent discussions are addressed in the attached technical memorandum and in the final HHRA, either in the main document, or in the response to comments and Appendices in the attached CD. In addition, a second objective of this letter is to explain how the State and EPA arrived at the risk management strategy proposed for the Basin. The State's position is that environmental work in the Basin is in the risk management phase. We hope that we can work together on risk management, focusing on community improvement for as little negative impact as possible.

Plans for remediation are responding to the fact that the upper Basin communities and recreational sites throughout the Basin contain lead concentrations in soil and dust that, with typical exposures, pose a risk to individual children that exceeds national standards. While the consequences of the lead concentrations in the soil and dust are far from a public health emergency, we can not deny the public health situation that exists. The lead levels observed are not expected to cause cancer or increased mortality. However, we continue to find that a substantial percentage of the young children tested in the Basin have blood lead levels greater than 10 μg/dl (16 % of preschoolers (1 to 5 yrs) tested from 1996 to 1999 and 17% in 2000). Blood lead levels greater than 15 μg/dl are measured in a few children every year. Lead is toxic to young children and can result in adverse neuro-cognitive effects.

Both the health risk of lead in soil and remediation often involves private property. The State has an obligation to communicate the risks and liabilities to the property owners. Superfund requires the government or responsible parties to develop a remediation strategy that minimizes health risks and the impacts on property values. The State's and EPA's objectives of the proposed risk management strategy for the Basin are:

- achieve national standards for risk of childhood lead absorption by reducing exposure for current as well as future situations;
- strike a balance between contaminated soil and dust remediation and long-term exposure controls that require on-going operation, maintenance, and participation in the programs;
- strive for consistency in the standards achieved among the communities, so that the future lead exposure concerns do not create inequities among Basin communities; and
- implement remediation and long-term controls with the least economic burden to private property owners and local governments in both the long and short term.

Risk Management Strategy: The HHRA was used in the risk management strategy to determine the maximum concentrations in soil and dust to which children can be exposed and still achieve the national blood lead standards. The risk management strategy proposes actions to break the exposure pathways from soil and dust to children. These actions are a combination of shallow removals of soil with lead greater than 1000 parts per million (ppm), capping of contaminated soil with clean soil, and vegetation of soil with concentrations between 700 ppm and 1000 ppm. The proposed cleanup threshold for developed recreational areas is 700 mg/kg. Other actions to lower exposure are reduction of lead in dust by paint abatement and remediation of fugitive sources, as well as education regarding practices that reduce ingestion and absorption of lead.

The comments on *EPA's Human Health Alternatives - Technical Memorandum (October 2000)* submitted by the Shoshone Natural Resource Coalition in December 2000 suggest that many in the communities are ready to participate in the education efforts and other long-term control measures. Because the risk management strategy relies most heavily on barriers to exposure rather than source removal, success of this strategy will require on going participation by the public and local governments.

It is the State's view that the proposed risk management strategy that was approved by the *Governor's Human Health Task Force* in December 2000 meets these objectives and can be accomplished with concerted effort in a few years at an affordable cost. It is believed that this proposed remedy presents a balance between removals and long-term institutional controls. Upon completion of the remediation and putting long-term controls in place, the communities are eligible for Superfund de-listing and lead exposure will no longer be a deterrent to local commerce. Additional benefits to the communities will be the local infrastructure projects included as part of the remedy, such as street and sewer improvements, curbs and gutters, and flood control measures. As the Basin becomes economically stronger, the links between poverty and lead exposure will decrease.

The State does not believe that the proposed risk management strategy in any way affects or detracts from the long and proud history of mining and other natural resource industries in the area, nor does it affect their current viability.

Blood Lead Survey Data: Blood lead data were used in the HHRA to support the use of site specific characteristics for assessing lead exposure such as bioavailability and dose-response rate. This ultimately led to the use of an 18% bioavailability estimate for soil and dusts, as opposed to the EPA default 30% value. That, in turn, resulted in a proposed action level for soil removal of 1000 ppm for residential yards rather than the EPA default value of 400 ppm.

The blood lead data were also used to estimate the relative contribution to childhood lead exposure from soil, dust and other sources. The regression analysis relating lead concentrations in environmental media to blood lead, conducted as suggested by mining company representatives, and follow up investigations of children with high blood lead levels all point to a relationship between blood lead and lead concentrations in soil and dusts. The regression analysis showed that house dust and yard soil were the greatest contributor to elevated blood lead levels. Lead in house dust comes from the yard soil, other soil and dust in the communities and deterioration of lead paint.

The decisions to use blood lead data for these purposes within the HHRA was a consensus reached among the State, EPA and mining company representatives. To maximize the number of blood lead analysis, all parties agreed to support an aggressive effort by the Panhandle Health District in 1999 to obtain additional blood lead samples and to combine the data sets from the annual surveys by the District with the 1996 ATSDR sampling. Although the ATSDR blood lead sampling was voluntary, analysis of demographic information suggested that the population that gave blood samples was not biased toward the factors that affect exposure such as income.

To obtain the additional blood lead data it was critical to secure the maximum possible participation in the August 1999 blood lead survey conducted in the Basin. This survey was successfully implemented, but unfortunately obtained only 25% participation, despite mining industry support and a $40 payment for blood. Corresponding soil and dust samples were collected from those participating homes in the fall of 1999.

We agree with your point regarding representativeness of the blood lead database. Because the available data may not represent the portion of the population that was not tested, the survey results were not used to quantify the risk or the probability of exceeding blood lead criteria for individual children. In fact, current federal policy discourages the use of blood lead surveys for this purpose and instead requires predictive modeling.

Securing a randomized survey of the Basin blood lead levels coupled with corresponding environmental exposure measurements would require a good deal of time and money, neither of which was available last year. Our concerns are that a new data set would be subject to many of the same criticisms as the current database, would delay the implementation and Superfund delisting, and not comply with EPA's policy of applying predictive modeling to individual properties to ensure sustained prevention. The State does not see a strong likelihood that continued study or the results obtained in a comprehensive blood lead survey would result in significantly different criteria for remediation.

Closing: While the science of health and environmental risk assessment is not perfect, the State believes that it is in the best interest of the communities and property owners to comply with the national criteria. The current policy and standards promulgated by Centers for Disease Control and Prevention and U.S. EPA have undergone a great deal of scrutiny and are continually reviewed. The federal Science Advisory Board (SAB), the highest level of review for the agency, notes in their preamble that:

The SAB recognizes that EPA is sometimes forced to take action to avert an emerging environmental risk before all of the rigors of scientific proof are met. To delay action until the evidence amounts to incontrovertible proof might court irreversible ecological and health consequences. In such cases, the Agency makes certain assumptions and extrapolations from what is known in order to reach a rational science policy position regarding the need (or lack thereof) for regulatory action.

The policies and procedures for managing lead exposure and the HHRA were extensively evaluated in recognized peer-review procedures pursuant to federal guidelines. At each level reviewed, the HHRA, the component analysis, and tools used were found scientifically valid and technically competent.

It is the State's position that there are many ways to implement remediation and control exposures to achieve the national standards. We believe that working with local governments and the public to figure out the best implementation strategy for the greater good of a community is our responsibility. We acknowledge that developing an implementation strategy is complicated by the fact that the perceptions are split among the local residents about the degree of risk from lead in soil and dust.

This split is shown by the responses to the question in a random survey commissioned by Idaho Department of Environmental Quality (DEQ) in fall 2000:

Lead contamination in the yards of homes in the valley is a serious health problem - do you strongly agree, somewhat agree, undecided, somewhat disagree, or strongly disagree?

Of the 200 respondents living in the Silver Valley or along the Coeur d'Alene River, 43% said they either strongly agreed or somewhat agreed, 15% were undecided, and 42% somewhat disagreed or strongly disagreed. The responses show more agreement with the statement among those living near Lake Coeur d'Alene in which, of 271 respondents, 57% strongly or somewhat agreed, 23% was undecided and 20% disagreed strongly or somewhat (IDEQ 2000).

Despite the differences of perceptions, we are committed to continue discussions and invite you to join us in the effort of developing the implementation strategy. We are committed to protecting our children's health and developing answers to the questions of how to reduce deterrents to conducting commerce, expand the economic base, stabilize property values, provide recreation opportunities, and in general how to get life back to normal in the shortest time possible.

Sincerely,

Rob Hanson
Mine Waste Program Manager
Idaho Department of Environmental Quality
TECHNICAL MEMORANDUM

ATTACHMENT to July 13, 2001 letter to Ivan Linscott, Chair, SNRC Science Forum

SUBJECT: **Response to Issues Raised at the Shoshone Natural Resource Coalition (SNRC) Science Forum, April 2001**

The concerns presented at the Science Summit and subsequent discussions have been considered and are addressed below under six general headings. The Coeur d'Alene Basin Human Health Risk Assessment (HHRA) has been modified to reflect particular issues noted in the response to comments.

1. HHRA Implementation Strategy: Many of your concerns address the data base and site-specific analysis of the blood lead data. The uses made of blood lead data in the assessment were pre-determined by the approach taken in implementing the HHRA. The HHRA implementation strategy was determined by the *Governor's Advisory Council on Human Health Risk Assessment* in 1999. The decision was to conduct the HHRA on an accelerated schedule in response to public and interested party demands that the process move forward as quickly as possible, and incorporate as much site-specific health information as was obtainable in that time frame.

The State originally decided to assume the lead in the HHRA because this phase of the investigations involved public health and private and public property issues. Protection of the public health is a traditional State government responsibility and the State and local Panhandle Health District (PHD) have a long history of implementing lead health programs in the area. Hundreds, to potentially more than a thousand, private, local government and State properties are contaminated in the Basin. CERCLA requires that each property be evaluated as to risk to human health and the environment and that owners and tenants be informed as to the determination. State law also requires homeowners and realtors to disclose "the known presence of hazardous materials or substances" about their property to prospective purchasers. Failure to disclose this information can result in lawsuits such as the one that is currently going to court based on a real estate transaction in Wallace.

The State spent considerable effort convincing the U.S. Environmental Protection Agency (EPA) that this approach was doable, and EPA agreed in a Memorandum of Agreement (MOA) in early 1999 to proceed in that manner. In order to complete the risk assessment quickly, it was necessary to i) use existing data, ii) implement all three suggested methodologies advocated by State, EPA and the Site PRPs, iii) identify as many areas of agreement as possible, and iv) defer as many issues as practicable to the risk management phase.

The three principal quantitative evaluation techniques applied are the default mode integrated exposure uptake biokinetic (IEUBK) model, regression analysis of the blood lead database against the lead concentrations of soil and dust and paint condition, and the IEUBK model using the site-specific bioavailability factor that was applied at the Bunker Hill Superfund Site (BHSS). The application of default IEUBK analysis is included as required by current USEPA guidance. The site-specific analysis that quantitatively relates blood lead levels to environmental media concentrations and dust lead levels to soil and paint variables was suggested by the site PRPs. The application of the IEUBK model with site-specific factors reflects the success of that technique in managing remediation and reducing blood lead absorption in the BHSS.

The HHRA is a consensus document reflecting the views of EPA and the State. It was agreed in the MOA negotiations that all available information that does not compromise individual confidentiality would be presented, and three approaches to analysis and evaluation of that information would be conducted and discussed. There are, of course, varying opinions and the HHRA has sought to present and discuss those objectively.

With regard to lead in soils and dusts, federal policy says that cleanup activities should reduce the probability of a child having a blood lead level of 10 μg/dl, or greater, to less than 5% at any *individual* property. The government has an obligation to take corrective action if current contamination levels exceed these criteria. Eventually each property owner will be informed as to the evaluation and, if warranted, given the option for corrective action. Every property owner and local government has the right and need to know the results of the assessment and the varying opinions regarding contaminant levels on their property.

The State and EPA do not have the discretion, nor the desire, to ignore these issues. Soils, dust and blood lead levels have been measured by recognized methods. Although the levels do not constitute a medical emergency, the concentrations are of concern. Health officials do not expect to see excess cancer or mortality. However, lead is a known neuro-toxin, and deficits in neurocognitive and neurobehavioral development are plausible at blood lead levels observed in Basin children.

The HHRA was developed ahead of the Remedial Investigation and Feasibility Study (RI/FS) in the Superfund Project. The results of the HHRA have been available for nearly a year and have served as a basis for public input and discussion of proposed remedies and clean up strategies. The State and EPA are negotiating a Proposed Plan that will be offered for public consideration as soon as the FS documents are complete. The accelerated HHRA has moved the overall process ahead by, at least, a year or more.

2. Risk Management Strategy: The *Governor's Advisory Council on Human Health Risk Assessment* also provided guidance regarding the preferred approach for risk management efforts. Although they did not indicate a preference for specific risk management actions, their directive was to accelerate the risk assessment process and provide for maximum public and affected party input to risk management decisions. The rationale expressed was that any required cleanup be accomplished quickly with as little disruption or impediment to commerce and economic development activities as practicable. In accomplishing this goal, it was important to obtain as much consensus as possible in the risk assessment process and proceed to resolve outstanding differences in the risk management forum where the public can have the most influence. In addition to the general benefits of a growing economy, emphasis on economic development is necessary to assist in reducing childhood lead exposure. Both the HHRA and subsequent draft Proposed Plan discuss the relationship between poverty and increased risk of lead exposure among children.

Cleanup objectives in the BHSS and those proposed for the Basin also recognized the importance of minimizing the detrimental effects of the Superfund stigma and using the cleanup to support economic development as an integral risk management tool. Much of the stigma problem is related to the public perception of the contamination problem and the associated health risks. Idaho Department of Environmental Quality (DEQ) has conducted surveys to assess

public perception of these problems. Regarding the question, "Lead contamination in the yards of homes in the valley is a serious health problem - do you strongly agree, somewhat agree, undecided, somewhat disagree, or strongly disagree." Of the 200 respondents living in the Silver Valley or along the Coeur d'Alene River, 43% said they either strongly agreed or somewhat agreed, 15% were undecided, and 42% somewhat disagreed or strongly disagreed. The numbers show more concern among those living near Lake Coeur d'Alene in which of 271 respondents 57% strongly or somewhat agreed, 23% were undecided and 20% disagreed strongly or somewhat.

It is recognized that substantial investment in local infrastructure will be required to maintain the remedies. It is hoped that infrastructure improvements combined with a protective consensus cleanup endorsed by State, federal and local authorities can resolve public concerns regarding the hazards associated with soil and dust contamination and promote investment in and redevelopment of the area.

3. Scientific Basis for Action: Several questions were raised regarding the scientific basis for the policies, procedures and methodologies implemented in the HHRA. You registered concern with i) the national policy that calls for remedial actions based on risk rather than demonstrated health problems, ii) with the scientific validity of the IEUBK Model for lead that is used for estimating risk, and iii) the application of the IEUBK model in the HHRA, and iv) the representativeness and use of observed blood lead data in the HHRA.

i) National Policy: Both federal risk assessment policy and, specifically, the use and application of the IEUBK model for human health lead risk assessment has been evaluated by the Science Advisory Board (SAB) and has been endorsed and approved for Agency use (USEPA 1989a, 1989b, 1989c, and 1990). In 1990, the SAB reviewed the overall application of lead related programs and policies throughout the agency and endorsed the use of the IEUBK in Superfund activities.

The SAB provides the highest level of scientific review and advice as may be requested by the USEPA Administrator, the Committee on Environment and Public Works of the United States Senate, or the Committees on Science and Technology, Interstate and Foreign Commerce, or Public Works and Transportation of the House of Representatives. Members of and Consultants to the Board constitute a distinguished body of scientists, engineers, and economists who are recognized, non-governmental experts in their respective fields. Generally, the Board functions as a technical peer review panel. The SAB conducts its business in public view and benefits from public input during its deliberations.

Through these proceedings, Agency positions are subjected to critical examination by leading experts in the field in order to test the currency and technical merit of those positions. At the same time, the SAB recognizes that EPA is sometimes forced to take action to avert an emerging environmental risk before all of the rigors of scientific proof are met. To delay action until the evidence amounts to incontrovertible proof might court irreversible ecological and health consequences. In such cases, the Agency makes certain assumptions and extrapolations from what is known in order to reach a rational science policy position regarding the need (or lack thereof) for regulatory action. Here, the SAB serves as a council of peers to evaluate the soundness of the technical basis of the science policy position adopted by the Agency.

Current federal policy is clear with regard to taking action to prevent disease based on risk, rather than requiring demonstration of health problems before responding. Environmental lead levels in soils and dusts in the Coeur d'Alene Basin are sufficiently high to warrant concern, based on both conventional and site-specific risk assessment, and high blood lead levels have been measured among young children most vulnerable to adverse effects.

USEPA policy requires risk to be characterized by environmental exposures such as lead concentrations in soil and dust. The USEPA policy goal for predicted risk has become more stringent over the past 10 years. Currently, the goal addresses individual risks for those children left at the highest exposure levels and recommends that the probability of experiencing a blood lead level of 10 μg/dl or greater, at any residence in the future, be less than 5%, and that no children exceed the 15 μg/dl blood lead criteria. Prior to 1994 the goal was applied across a community. Since then it is to be applied to individual properties.

ii) Validity of the IEUBK Model:

The approved method to estimate this risk is use of the IEUBK model for lead. Other predictive models may be used, if shown to be equivalent. No other published biokinetic models are currently considered equivalent in all their features for technical and regulatory application to risk assessment at CERCLA sites. Only the IEUBK is currently approved for use (USEPA, 1994; USEPA, 1998).

The IEUBK model is a product of nearly 20 years of development within the USEPA. The initial efforts to model lead emerged from the Office of Air Quality Planning and Standards with the development of the National Ambient Air Quality Standard for Lead and subsequently from the Office of Water in the National Primary Drinking Water Regulation for Lead (U.S. EPA, 1986) (U.S. Environmental Protection Agency, 1991). Both of these offices employed mathematical modeling to estimate the impact of lead on child blood lead levels. (Zaragoza & Hogan, 1998a). Subsequent to the SAB review of the IEUBK model and its use in risk assessment, policy guidance consistent with the SAB advisories was issued by the Office of Solid Waste and Emergency Response (OSWER) regarding the use of the IEUBK model in risk assessment at Superfund sites. The original guidance has been updated in two subsequent directives. (USEPA 1989a, 1989b, 1989c, 1994, and 1998).

Pursuant to SAB recommendations that the USEPA continue to improve the performance and application of the IEUBK, the National Center for Environmental Assessment (NCEA) has conducted a series of international workshops addressing specific aspects of lead health risk assessment and risk management activities at lead-related hazardous waste sites. Those workshops included specialized topics regarding exposure assessment, bioavailability, model validation, and remedial effectiveness. Representatives of the State and EPA project teams have attended and presented at each of these conferences and the last was convened in Coeur d'Alene in May 2000, with several presentations and critiques relative to the BHSS and Coeur d'Alene Basin (USEPA 1995a). An extensive compilation of publications on the validation and performance of the IEUBK Lead Model were published in Environmental Health Perspectives, Volume 106, Supplement 6, December 1998 (Bowers and Cohen 1998, Carroll and Galindo 1998, Fowler 1998, Hogan et al 1998, Maddaloni et al 1998, Mahaffey 1998, Marcus and Elias

1998, Mickle 1998, Mumtaz et al 1998, Mushak 1998a and 1998b, O'Flaherty 1998, Oreskes 1998, Pounds and Leggett 1998, Rabinowitz 1998, Succop et al 1998, and White et al 1998).

iii) Application of the IEUBK Model in the HHRA: The USEPA has also recognized the evolving body of knowledge regarding lead health risk assessment at hazardous waste sites and has designated internal oversight groups to monitor and assess application of the IEUBK model and pursuant risk assessment and risk management decision-making in agency regulatory activities. The *Lead Sites Consultation Group (LSCG)* is comprised of senior management representatives from the Waste Management Divisions in all 10 EPA regions along with senior representatives from the Office of Emergency and Remedial Response in EPA headquarters. The LSCG is supported by EPA's *Technical Review Workgroup (TRW)* for lead and the national *Lead Sites Workgroup (LSW)*. The TRW consists of key scientific experts in lead risk assessment from various EPA Regions, labs and headquarters. The LSW is comprised of senior Regional Project Managers from various Regions and key representatives from headquarters who are experienced in addressing lead threats at Superfund sites.

The TRW monitors the technical aspects of the IEUBK model and reviews applications of the model for consistency with agency guidance regarding lead health risk assessment. *The TRW has extensively reviewed the HHRA and found it scientifically competent and compliant with agency policy. The TRW review is included in the response to comments for the Public Draft HHRA (Maddaloni and Koporec, 2000).*

The LSW is made up of site managers from lead-related Superfund sites throughout the nation. The group meets periodically to review application of agency requirements at various sites for national consistency and to share experience. *This group convened in Coeur d'Alene in May 2000 and reviewed the application of the IEUBK and subsequent risk management and remedial effectiveness evaluations at the BHSS. Their findings concurred with the appropriate application of science and technology compliant with agency policies at the BHSS.*

The components of the HHRA including the IEUBK and Adult Model analysis techniques, application of site-specific data and the document itself has received extensive review within these procedures. At each level of review the HHRA and the component analyses and tools used, have been found to be scientifically valid and technically competent.

iv) Use of Blood Lead Surveys in Lead Risk Assessment: Current USEPA guidance for using blood lead studies and IEUBK model at lead sites emphasizes the use of the IEUBK model for estimating risks for childhood lead exposure from a number of sources, such as soils, dust, air, water, and other sources to predict blood lead levels in children 6 months to 84 (7 years) months old. The policy on the appropriate use of the IEUBK and blood lead studies is that the IEUBK model be used as the primary tool to generate risk-based soil cleanup levels at lead sites for current or future residential land use. If an alternative method for generating cleanup levels is proposed, the approach must be submitted to the national Lead Sites Consultation Group (LSCG) for review and comment. Response actions can be taken using IEUBK predictions alone; blood lead studies are not required. Blood lead studies and surveys are useful tools at lead sites and can be used to identify key site-specific exposure pathways and to direct health professionals to individuals needing immediate assistance in minimizing lead exposure; however, it is

recommended that blood lead studies not be used for establishing long-term remedial or non-time-critical removal cleanup levels at lead sites.(USEPA, 1994; USEPA, 1998).

4. Use of the Basin Blood Lead Survey Data in the HHRA: The HHRA strategy relied on utilizing the existing and supplemental data. Existing blood lead data included the 1996 ATSDR Exposure Study data and the Panhandle Health District lead health surveys. Lead concentrations in soil and in other environmental media were taken from the 1996 Study, the Natural Resource Damage Assessment (NRDA) and Remedial Investigation and Feasibility Study (RI/FS) databases and EPA's emergency removal program. A sampling program was developed to produce supplemental blood lead data and corresponding media lead concentrations in the residential environment. This sampling plan was reviewed by the PRPs and contained a protocol to quantitatively address lead paint contributions. In order to conduct the site-specific quantitative analysis of the relationship between the concentrations of lead in soil, dust and paint and blood lead levels in children that was advocated by the PRPs, it was critical to secure the maximum possible participation in this sampling effort. The blood lead survey took place in August 1999 soil and dust sampling in the respondents' homes were done in the Fall of 1999. Unfortunately this blood lead survey obtained only 25% participation of children in the Basin , despite mining industry support and a $40 payment for blood.

The State and USEPA acknowledge, as many critiques have pointed out, that the paired blood lead/environmental exposure database available for the Basin and has not been demonstrated to be representative of the overall population. Opinions vary as to whether these data over- or under-estimate excess lead absorption among non-participants. Blood lead samples were not solicited for experimental or survey purposes. Blood lead samples are observational and opportunistic based on voluntary participation in health response programs. As a result, blood lead levels are not, nor were ever, intended to be randomized. The blood lead database is estimated to have tested less than 1/3 of the 9 month to 9 year old population and less than 20% of pre-school children. Health officials are concerned that there may be many children in the Basin with high blood lead levels whose parents are not availing themselves of testing and follow up services.

Although the blood lead database was not used to quantify risk, it was used to develop site-specific parameters for the IEUBK Model that support lesser predicted clean up needs for the Basin. EPA's policy requires that default exposure and absorption parameters are used in the IEUBK analysis, unless there is compelling evidence for the use of site-specific parameters. Default parameters are reflective of typical national conditions and application of these factors results in required cleanup criteria for soils and dusts near 400 mg/kg lead. This effectively serves as a default national cleanup standard that can be amended higher or lower based on site-specific information. The use of a site-specific value rather than the default resulted in a action level for residential yard surface soil removal of 1000 ppm lead rather than the EPA default value of 400 ppm.
The blood lead data was also used to estimate the relative contribution to childhood lead exposure from soil, dust and other sources. The regression analysis between lead concentrations in lead, dust and paint and blood lead data, conducted as suggested by the PRPs, and follow up investigations of children with high blood lead levels all point to a relationship between blood lead and lead concentrations in soil and dusts. The regression analysis showed that house dust and yard soil were the greatest contributor to elevated blood lead levels. Lead in house dust

predominantly comes from the yard soil, community soil and dusts and deteriorating of lead paint.

The decisions to use blood lead data for these purposes within the HHRA was a consensus reached among the State, EPA and PRPs, although it was well recognized that the blood lead data set was not from a randomized survey of the Coeur d'Alene Basin.

Because the database for blood lead levels may not be representative of the overall population, the blood lead survey results were not used to quantitatively assess the risk or probability of exceeding blood lead criteria in this population, especially for young children. This limitation was overcome in the Box, where annual participation rates are near 50% and reasons for failure to participate are known for the majority of the remaining resident children (see Appendix Q of the HHRA). Turnout and identification of reasons for non-participation are insufficient in the Basin to assess the representativeness of the blood lead database.

Although the blood lead database may or may not represent the overall population, a representative sample of environmental media was obtained in 1996 that has been substantially supplemented to near 50% of all potentially affected homes in the Basin. The Agency for Toxic Substances and Disease Registry (ATSDR), in their analysis of these data, showed that the 1996 blood lead survey was not biased among participants and non-participants with regard to socio-economic co-factors that affect exposure such as income (IDHW and ATSDR 2000). Moreover, comparison of the environmental exposures for those children that have provided blood lead samples to the overall environmental database, shows no obvious differences in exposure media concentration. This suggests that any suspected biases in the population providing blood lead levels are likely not media-contaminant concentration or socio-economically related, but reflect personal choices not to participate.

Since release of the Public Draft of the HHRA, the State has argued that there is sufficient site-specific evidence to support the use of reduced dose-response parameters for the Basin that could result in higher cleanup levels. This argument is based on the experience and success of using these same adjustments in risk management activities at the Bunker Hill Superfund Site, and analysis of the existing blood lead and environmental database for the Basin. These results suggest that soil and dust cleanup criteria in the range of 800 mg/kg to 1000 mg/kg in combination with community greening activities (vegetative cover) in the range of 600 mg/kg to 800 mg/kg will be protective, and is in compliance with EPA guidance.

5. Use of Site-specific Bioavailability, Soil/Dust Sieving: Your group has correctly noted that the reasons for reduced dose-response relationships justifying higher site-specific clean up limits for soils and dusts are bioavailability, soil/dust sample characterization and ingestion rates. Concerning bioavailability, your group suggests that the mining industry derived lead in soils and dusts is galena and is insoluable and not bioavailable to children. The State and EPA believe this position to be inconsistent with data from other mining sites as well as the Coeur d'Alene Basin. Bioavailability studies on mine waste material from Colorado, Montana and Utah suggest that secondary mineralization results in a lead bioavailability midway between galena and the more soluble minerals. A medium bioavailability is consistent with the site-specific application of the IEUBK model used for the HHRA. This is also consistent with the leachate tests conducted on various soils including floodplain tailings at the BHSS that show lead is dissolved in varying proportions from soils in acidic solutions. In addition, the regression analysis of the site-specific dose-response data that is in the HHRA as suggested by the PRPs, and follow up investigations of children with high blood lead levels all point to a relationship between blood lead and lead concentrations in soil and dusts. Please see Sections 6 and 7 and Response to Comments in the HHRA and the 1999 Five Year Review Addendum and Extended Response to Technical Comments (TerraGraphics 2001).

The sieving procedure used at the site is consistent with national guidelines based on review of appropriate studies regarding the adherence of particles to children's hands. This protocol is predicated on the experience that even a small proportion of fines in a bulk soil is sufficient to adhere to a child's hand. Please see Sections 2 and 7 and the Response to Comments in the HHRA for details.

The soil sampling protocols used in the Basin evolved from those employed at the BHSS. The techniques were originally designed, and have been progressively modified, to provide a composite or aggregated sample of those soils that children contact in the course of the day. This technique is designed to acquire "average values" and was specifically criticized in HHRA comments for not targeting "hot spots" Originally, four samples were taken at a home and separately analyzed at the laboratory - the front and back yards, the drip line along the side of the home and any play areas. These results were compared individually and in aggregate to blood lead levels. Subsequent experience indicated that a combination of the front and back yards sample, composited and run only one time at the laboratory, provided and equivalent measure and was considerably less expensive to obtain. That protocol was employed in the 1996 State/ATSDR survey. EPA re-employed a multi-sample approach in 1997-99, that was also shown to be equivalent to the compositing technique in subsequent analysis. The current yard sampling protocol employed in the Box was developed by the BHSS PRPs and was agreed to by the governments in Consent Decree negotiations. We believe the personnel that developed the protocol are still employed at the local offices of ASARCO and McCully, Frick, and Gilman. You might contact them for details regarding any investigations they performed regarding compositing and aliquot volumes, etc.

***6.* Summary:** In the interest of accelerating the CERCLA process and achieving national standards with respect to lead health risk in the Basin, the State and EPA agreed that a consensus risk assessment be completed as quickly as practicable. In order to meet these requirements the *Governor's Advisory Council on Human Health Risk Assessment* agreed that the HHRA follow current federal guidance and incorporate as much site-specific health information as was obtainable in that time frame.

Current federal policy requires that potential future risks be evaluated, that predictive modeling techniques be employed, that national default parameters be used unless compelling evidence supports site-specific factors, that the criteria be applied to individual properties, and that preventative remedies be employed as corrective actions. In meeting these requirements it was determined that the HHRA i) use existing data, ii) implement all three suggested methodologies advocated by State, EPA and the Site PRPs, iii) identify as many areas of agreement as possible, and iv) defer as many issues as practicable to the risk management phase.

The USEPA has designated internal oversight groups to monitor and assess application of the IEUBK model and pursuant risk assessment and risk management decision-making in agency regulatory activities. The components of the HHRA including predictive modeling techniques, application of site-specific data and the document itself has received extensive review within these procedures. At each level of review the HHRA and the component analyses and tools used, have been found to be scientifically valid and technically competent.
It must be noted that this evidence conclusively shows that, at least, the sampled population is at-risk of excessive blood lead levels. This is demonstrated both in the Default and "Box"

applications of the IEUBK model, the quantitative analysis of the site-specific dose-response data, by direct blood lead measurements, and by follow up investigations of individual children with high blood lead levels.

Responsible health agencies are compelled to act, at a minimum, in the interest of the sampled population and those children exhibiting dangerous blood lead levels. Because the remainder of the population, that has not been tested, is similarly exposed (ie. have similar soil and dust concentrations in their homes) and these children may exhibit similar behaviors and socio-economic status, current policies require they be protected as well.

The State is concerned, that considering the prevailing opinions regarding the health significance of high blood lead levels, re-opening this assessment may well move the conclusions toward a more intrusive cleanup with little overall improvement in risk reduction. The importance of primary prevention of lead exposure has been highlighted by recent studies indicating adverse health effects at blood lead levels below 10 micrograms per deciliter (µg/dl) and the failure of chelation treatment to prevent cognitive impairments in treated children (Lanphear et al., 2000; Rogan, et al., 2001; Rosen and Mushak, 2001). The environmental lead levels measured in the Basin may well, in the future, become a greater concern from the national perspective.

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